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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,426	07/16/2003	Tong-Shui Zhou	USP2151C-DRSH	1741

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EXAMINER	
MCCORMICK EWOLDT, SUSAN BETH	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,426	ZHOU, TONG-SHUI	
	Examiner	Art Unit	
	Susan B. McCormick-Ewoldt	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *1-24,33 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III in the reply filed on December 20, 2004 is acknowledged. Applicant did not respond to the election of species requirement. However in view of the prior art, the election of species requirements is withdrawn. Thus, the response file December 20, 2004 will be considered fully responsive.

Claims 1-24 and 33-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected claims, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 20, 2004.

Claims Pending

Claims 25-32 will be examined on the merits and claims 1-24 and 33-34 are non-elected claims.

Claim Objections

Claims 26 and 30 are objected to because of the following informalities: there is no period at the end of the claims. Appropriate correction is required.

Claim 25 is objected to as being dependent on a non-elected claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claim 29 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating blood diseases, does not reasonably provide enablement for preventing blood diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re* Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in

Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is "undue," not "experimentation." " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicted on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case, are discussed below.

Applicant's claims are directed to treating and preventing blood diseases. As discussed below, the definition of blood diseases is unclear. Inventions targeted for preventing blood diseases bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is high for such inventions because effective treatments for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because as the state of the art stands, there is no "prevention" or "cure" for blood diseases. Thus, claims to prevention may be unbelievable in the absence of strong supporting evidence. It is noted that the instant claim encompasses blood diseases that can be prevented or reduced, and yet the instant specification no guidance that would permit the skilled artisan to use the invention.

In the instant case, Applicant has disclosed that the claimed composition is useful in preventing blood diseases. The claim specifically disclose preventing blood diseases in a human, Applicant provides no guidance that would permit the skilled artisan to practice the invention commensurate with the *scope* of the instant claim. Also, in addition, the claim also encompass

using flavonoid extract which is clearly beyond the scope of the instantly disclosed/claimed invention.

One must consider the guidance provided by the instant specification and the prior art of record. As stated *supra*, the state of the art is unpredictable as it reflects that there is no prevention of blood diseases. Although the present claim recites "prevention," prevention is deemed to be a "cure" since prevention of a disease is interpreted to mean that the disease will entirely cease to manifest after administration of the composition.

It is noted that there is not a single example in the instant specification, *working or prophetic*, which indicates that the product of the instant disclosure would prevent blood diseases. For example, the data found in the specification is inconclusive to support the breadth of the claimed invention. Taking the examples of pages 10-18 into consideration, it appears that Applicant has found that the *Typhae* flavonoid extract does have some effect on treating blood diseases. However, again, there is no indication that this response can be reasonably extrapolated to blood disease treatment or prevention, or any other type of treatment or prevention.

Again, the claim is drawn to specifically preventing blood diseases. However, Applicant has not demonstrated the effectiveness of *Typhae* flavonoid extract on blood diseases. The skilled artisan would not have a reasonable expectation that the response displayed in the instant specification would reasonably extrapolate to prevent blood diseases lacking substantial evidence in the specification as well as the prior art pertaining to the efficacy of *Typhae* flavonoid extract.

The high degree of unpredictability associated with the claimed method underscores the need to provide teachings in the specification that would provide the skilled artisan with specific treatment regimens that achieve a therapeutic benefit; however, the specification does not provide such guidance and fails to provide evidence that *Typhae* flavonoid extract actually treat blood diseases. Without such guidance in the specification and the lack of correlative working examples, the claims would ***require an undue experimentation without a predictable degree of success on the part of the skilled artisan***.

In re Fisher, 427 F.2D 833, 166 USPQ 18 (CCPA 1970), held that "inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some ways on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; ***however, he***

must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (emphasis added).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 25, Applicant states "blood diseases" yet there is no definition of what blood diseases are in the specification. It is unclear as to what "blood diseases" encompass. Clarification is needed.

Claim 25 recites the limitation "said blood diseases" in line 2. There is insufficient antecedent basis for this limitation in the claim.

In claims 25 and 29, it appears that "flavonoides" is misspelled. Correction is needed.

In claims 26 and 30, it is unclear as to what Applicant is meaning with the recitation "diseases of blood vessel in brain and heart." Clarification is needed.

In claim 27 and 31 Applicant states that blood diseases "are selected from the group consisting of chest pain, stomachache, physical injuries, puerperium pain and menstruation." However, these are not considered diseases. Clarification is needed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over the websites http://www.ibiblio.org/pfaf/cgi-bin/arr_html?Typha+angustifolia&CAN=COMIND and http://www.itmonline.org/arts/pain.htm in view of Ishida *et al.* ("Studies on the Antihemorrhagic Substances in Herbs Classified as Hemostatics in Chinese Medicine. IX. On the Antihemorrhagic Principles in *Typha lactifolia* L.") and JP 06172196 A (translation provided).

A method of treating patients with blood diseases by administering flavonoids extract is claimed.

The website http://www.ibiblio.org/pfaf/cgi-bin/arr_html?Typha+angustifolia&CAN=COMIND discloses that pollen of *Typha angustifolia* (i.e. cat-tails) is used for an emmenagogue and haemostatic. Emmemagogue is an agent that promotes menstrual discharge and haemostatic means acting to stop the flow of blood. The website does not specifically disclose specific blood diseases (page 2 under "Medicinal Uses").

The http://www.itmonline.org/arts/pain.htm discloses that pollen from *Typha angustifolia* and *Typha latifolia* is rich in flavonoids and has been associated with improving blood circulation (page 2, first paragraph).

Ishida *et al.* ("Studies on the Antihemorrhagic Substances in Herbs Classified as Hemostatics in Chinese Medicine. IX. On the Antihemorrhagic Principles in *Typha lactifolia* L.") disclose the use of flavonoids that known to have antihemorrhagic principles in herbs that are classified as hemostatics in Chinese medicine (page 4414, first and second paragraphs).

JP 06172196A discloses using ethanol and heat for extracting *Typhae* pollen (i.e. bulrush) to be used in improving blood circulation ([0018] and [0019]). This extraction encompasses the extraction taught by Applicant in the specification. Therefore, this extraction would contain the flavonoids as claimed in claim 1.

From the teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. One would have been motivated to extract the flavonoids from *Typha* pollen, as suggested in JP 06172196 A, to help improve blood circulation and internal bleeding as taught by the additional cited references.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Summary

No claim is allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan D. Coe
2-18-05

sbme

SUSAN D. COE
PATENT EXAMINER